EDF COMMENTS FOR EPA IRIS STAKEHOLDER PANEL, 11-13-12

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The theme of my comments today is the critical need to restore balance to the IRIS program. In my view, the program's structure and practice have over time tilted badly toward allowing one set of interests and desirable attributes of chemical assessments to wholly dominate over another, equally critical set. Let me explain.

Scientific quality vs. Timeliness

I'll start with one pair of competing objectives: on the one hand, to ensure that assessments and their underlying data are of high scientific quality; and on the other hand, to ensure assessments are timely and do not unduly delay actions needed to address risks.

IRIS has repeatedly allowed the demands for more and more "certain" data to essentially indefinitely delay completion of it assessments. Despite the goal IRIS set in 2009 of completing most or all assessments in 23 months – and adhering to deadlines for each step in the IRIS process that would allow it to meet that goal – not a single assessment issued since then has met that timeline. *Nor have any of them met any of the deadlines for the individual steps in the process*. The average completion time of these assessments, according to GAO, has been *7.5 years – nearly four times longer than the program's goal of 23 months*.

These delays have profound real-world consequences: They allow continued exposure and harm to health from the subject chemicals – because decisions that rely on IRIS are also delayed: ***Simply put, a decision delayed is health protection denied.***

As the National Academy of Sciences (NAS) stated in its 2009 report *Science and Decisions* (page 72): "The design of a risk-assessment process should balance the pursuit of individual attributes of technical quality in the assessment and the competing attribute of timeliness of input into decision-making."

The fact is scientific information is ALWAYS incomplete and evolving. Assessments must – in all but the most exceptional of circumstances – be based on *information already at hand*. The

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practice of waiting for one more study to be completed, as has happened repeatedly under IRIS – especially when that study is to be conducted by an entity with a vested financial interest in tilting the outcome – simply must stop.

Of course, the science will evolve and improve over time; the best way to accommodate this reality is through a robust process for updating IRIS assessments periodically over time.

Realistic but aggressive timelines must be set – and rigorously adhered to. In their absence, *all* of the incentives are toward delay. And under our system where a pending assessment means no action can be taken, ***all of the rewards of delay fall to one side – the (un)regulated industry – and all of the risks fall on the public***.

Clear consequences must follow if deadlines are missed; two options that I support are first, reliance on conservative interim default risk values and second, restrictions of expanding production and use of a chemical, pending completion of its assessment. Such measures will ensure that the incentives point toward timely completion of assessments, and that risks arising from continued exposure to such chemicals are at least not increased before those risks are quantified.

A robust tracking system that accurately reports the precise status of each IRIS assessment from start to finish – and flags and clearly explains the reason for any delay – is essential to ensure an accountable process.

Transparency and "due process" vs. Ensuring balanced input

This is the second set of competing interests. Over time, with some ups and downs, the tendency for IRIS has been to respond to criticism by adding more steps to its process for conducting assessments. The result is a process that is, again, badly out of balance.

It may seem strange to hear this from a representative of the public interest community, but what IRIS needs is fewer, not more, opportunities for "public" input. It's indisputable that a more involved process with more steps is a major contributor to the delays that have plagued the IRIS program. But the problem goes deeper than that: More opportunities for input not only require more time, they also result in a process that virtually ensures the input received by EPA is imbalanced and badly skewed toward the regulated community.

Because companies that produce and use each chemical to be assessed – and the trade associations that represent them – have a clear vested financial interest in the outcome of the assessment, that factor will not surprisingly affect the content of their input. But it will also ensure they can and will take advantage of each and every opportunity for input they are provided. *We simply must stop pretending that there is a level playing field.* It is a certitude

that the affected industry will be better represented than other stakeholders at each opportunity for input, and the more such opportunities, the greater the imbalance becomes.

Rather than adding more steps, what is needed is *a further consolidation of the IRIS process*. Input should be solicited in one step at the beginning of the process – to get stakeholder input on the scope of the assessment; to identify key issues, available data and data gaps, and so on. Once a draft assessment is completed, a second round of input should be solicited, again in one step, on the draft, questions that the peer review should address, and so on. EPA should then consider that input in proceeding to finalize and issue the final assessment. Such a process will provide ample opportunity for input and due process, while reducing the imbalance in the type of input EPA receives.

Final observations

Finally, I feel compelled to offer my view, based on years of working in this arena, that the chemical industry has never shown real interest in actually seeing the IRIS program succeed.

How else does one explain its long history of seeking to delay or undermine IRIS assessments? Or the American Chemistry Council's demand that ALL draft IRIS assessments be sent to the NAS for review, knowing full well that this step will add upwards of $1 million and at least two years to each review? Even that's not enough for ACC: It also is demanding that ALL revised IRIS documents be sent back AGAIN to NAS for yet another review, with the same price tag and delay.

Nor is IRIS the sole target of this chemical industry assault on independent government science. ACC and its allies in Congress:

- have attacked the National Toxicology Program for having the backbone to list formaldehyde and styrene – two of the industry's biggest cash cows – as known and anticipated human carcinogens, respectively;
- have attacked voluntary government and private-sector standards that identify and reward use of less toxic chemicals in products and building materials, notably the U.S. Green Building Council's LEED program and EPA's Design for Environment program; and
- are pushing legislation that would exclude or restrict academic scientists who receive government research funding from serving on agency scientific review panels (falsely asserting such funding creates a conflict of interest).

There is a consistent pattern here. It is time it is called out for what it is: A concerted and sustained effort by the chemical industry that is *thinly veiled by its disingenuous rhetoric wrapping itself in the mantle of greater transparency and sound science*. That effort seeks to

place the industry's financial interests above the protection of public, community, consumer and worker health.

The IRIS process must take steps to ensure it serves the agency's mission to protect human health and the environment – by restoring balance to a process that has for far too long been skewed to favor the industry's narrow interests over those of the public.